EXECUTIVE SUMMARY

PURPOSE

To determine whether the Clinical Laboratory Improvement Amendments of 1988 have restricted the availability of laboratory services to Medicare patients.

BACKGROUND

In February 1992, the Health Care Financing Administration (HCFA) issued regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA). These amendments extended Federal regulation to all sites, including a significant number of physician office laboratories (POLs) and other sites that had previously been exempt from Federal regulation. The passage of CLIA has raised concern that laboratory sites, especially POL sites, might cease operations and thus restrict patient access to certain types of laboratory tests. Concerned about this possibility, HCFA requested that we conduct this study.

FINDINGS

Since passage of CLIA in 1988, the volume, number of tests per patient and expenditures have increased rapidly. Growth seems to have slowed after implementation in 1992, but data is incomplete.

The number of laboratory tests used in patient care has risen consistently since 1983. In 1983, Medicare paid for an estimated 139 million laboratory tests. In 1988, the year in which CLIA was passed, Medicare paid for 232 million laboratory test; today, Medicare pays for more than 403 million tests annually. The number of laboratory tests provided to Medicare Part B enrollees has more than doubled from five tests per enrollee in 1985 to an estimated 12 tests per enrollee in 1993.

The CLIA appears not to have affected physician ability to secure laboratory services for their patients.

None of the 232 physician practices, including the rural practices, contacted during this study indicated that they had any trouble securing laboratory tests for their patients. All had access to a laboratory and nearly all (98%) used more than one laboratory to perform testing. We found that the number of physicians having access to an in-office laboratory has remained unchanged since 1988 even though the actual number of POL sites operated by them has decreased. This is, in part, due to the consolidation of medical practices that has resulted in larger physician groups.

Only 38 counties in the United States have no physician medical practices and no laboratories. While POL sites are not as common, rural counties have 7.4 hospital laboratory sites per 100,000 persons versus 5 such sites per 100,000 population in non-rural counties. Since hospital sites are more likely to perform moderate and high complexity testing, persons living in rural areas appear to have available to them laboratory sites equivalent to their non-rural counterparts.

Physicians who changed their in-office laboratory operations were influenced by factors broader than CLIA; these influences include other government regulations and non-government factors, such as sales, mergers and managed care.

Of the 232 physician practices we contacted in our 2 random samples, 18 had closed a POL site and 8 had opened new sites. Eleven primarily cited governmental regulations as reasons for closure, three cited governmental and non-governmental factors, and four cited primarily non-governmental factors. The governmental factors included the Stark Amendments, Occupational, Safety and Health Administration requirements, CLIA and/or other government initiatives. Physician decisions to close an in-office laboratory were often not attributable to a single cause but to the cumulative effect of multiple factors.

Non-government factors have also caused some laboratory operators, including POLs, to re-evaluate the kinds of testing they offer and the number of sites they operate. Between 1988 and 1994, non-government factors appear to have affected physician in-office laboratories. Of the 232 practices we contacted, 64 volunteered information about the sale, merger, or changes in their practices. Of these, 30 noted non-government factors as the major reason for change in their in-office laboratory operations. These changes were the primary influence in their decision to close their in-office laboratory or to limit the kinds of testing they perform.

The CLIA appears to have affected the type of testing performed in POLs. Growth in the volume of tests billed by POLs appears to have slowed. Shifts from moderate and high complexity test procedures to waived testing procedures are evident in glucose, sedimentation rates and other areas of testing. While volume for some other procedure codes billed by POLs has declined, this decline was also experienced by all laboratories billing these codes; thus, indicating that factors other than CLIA may have influenced volume.

COMMENTS ON THE DRAFT REPORT

We received comments on our draft report from the American Medical Association, American Society of Internal Medicine, American Clinical Laboratory Association and HCFA. Based on comments we received, we have reordered and reworded the report findings. The full text of comments received can be found in Appendix E.

The HCFA and the American Clinical Laboratory Association concurred with our report findings. The American Medical Association and the American Society of Internal Medicine pointed out that our study does not address CLIA's impact on patient convenience or the speed and quality of testing afforded by physician in-office laboratory testing. While important subjects, these issues were beyond the scope of our inquiry which was simply to determine whether CLIA has restricted the availability of laboratory services.